JUL 27 2005

K050651

Summary of Safety and Effectiveness
Medtronic Orthopaedic Trauma Application

I. **Manufacturer**

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517

II. **Contact**

Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation, Inc.

III. **Product Name / Classification**

Common Name: Stereotaxic instrument
Classification Name: Instrument, Stereotaxic
Trade Name: Medtronic Orthopaedic Trauma Application
Stereotaxic instrument - Class II as described in 21 CFR § 882.4560
Product Code: HAW

IV. **Date Summary Submitted**

March 11, 2005

V. **Description of Device Modification**

The Medtronic Orthopaedic Trauma Application software combines existing FluoroNav (K990214) and Orthopaedic Hip (K021980) applications used to assist surgeons with the stabilization and repair of orthopaedic fractures.

VI. **Substantial Equivalence**

The Medtronic Orthopaedic Trauma Application is substantially equivalent to the combination of the FluoroNav (K990214) and Orthopaedic Hip (K021980) applications and is also substantially equivalent to the BrainLab VectorVision Trauma application (K012448). As required by risk analysis, all verification and validation activities performed by designated individuals and the results demonstrated substantial equivalence.

VII. **Indications for Use**

The Orthopaedic Trauma Application is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Orthopaedic Trauma Application is indicated for trauma procedures in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, pelvis or vertebra can be identified relative to a CT or MR based model, digitized landmarks or fluoroscopy images of the anatomy

- Acetabular, femoral and tibia fractures
- Guide Wire placement
- Implant/Hardware Removal
- Intertrochanteric Fractures
- Intramedullary Nailing
- Long-bone Fracture Fixation
- Long-bone Fracture Reduction
- Pelvic Fracture Fixation
- Pelvic Fracture Reduction
- Screw/Implant Placement
- Tibial, Femoral and Acetabular Osteotomies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Ms. Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K050651
Trade/Device Name: Medtronic Orthopaedic Trauma Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 5, 2005
Received: July 6, 2005

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, MS
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K050651

Device Name: Medtronic Orthopaedic Trauma Application

Indications For Use: The Orthopaedic Trauma Application is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Orthopaedic Trauma Application is indicated for trauma procedures in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, pelvis or vertebra can be identified relative to a CT or MR based model, digitized landmarks or fluoroscopy images of the anatomy

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- Pelvic Fracture Reduction
- Screw/Implant Placement
- Tibial, Femoral and Acetabular Osteotomies

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050651